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TITLE: Development of Predictive Models of Injury for the Lower Extremity, Lumbar, and Thoracic Spine after Discharge from Physical Rehabilitation

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The objective and overall hypothesis is that service member performance on a battery of physical performance tests performed upon discharge from medical care back to full duty, will be able to predict 1) the risk of sustaining any injury as well as 2) the risk of reoccurrence of the same injury. A two-pronged injury prevention approach is required to optimize return to duty rates after injury: Screening for known preventable musculoskeletal risk factors and ensuring these risk factors are mitigated prior to discharge from medical care. The current assumption is that a service member discharged from medical care is ready to return to full duty. Because history of prior injury is a well-established risk factor, every service member that is discharged from medical care after a musculoskeletal injury is already at a higher risk for future injury. Identifying those at increase risk of recurrence provides the ability for secondary and tertiary prevention programs to optimize return to duty rates. **Hypothesis 1:** Risk factors shown to be predictive of lower extremity and lumbar/thoracic spine injuries in other populations and in healthy service members will also be predictive of re-occurrence of original injury, future injury, and return to duty rates in service members being discharged from medical care. **Hypothesis 2:** The injury prediction models will vary by age and sex. **Hypothesis 3:** A multi-factorial prediction model that accurately predicts risk of new and recurring injuries, as well as return to duty rates, will consist of multiple variables.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT Unclassified	**b. ABSTRACT** Unclassified	**c. THIS PAGE** Unclassified	Unclassified	9	**19b. TELEPHONE NUMBER** *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

Table of Contents

INTRODUCTION: Musculoskeletal injuries have a significant deleterious effect on Soldier readiness. Screening algorithms for injury risk have been identified, but have not been evaluated in service members returning to duty after an injury. As past injury and pain with movement are strong risk factors for future injury, the ability to adequately screen a service members for injury risk after they have been cleared to return to duty from an injury is of great importance. The purpose of this project is to determine if performance on a battery of functional tests after discharge from medical care, can predict risk for injury after returning to full duty following a spine or lower extremity injury.

KEYWORDS: Injury prevention, injury prediction, injury risk, musculoskeletal, lower extremity, spine, return to duty

ACCOMPLISHMENTS:

What were the major goals of the project?
Milestone 1: IRB approval and HRPO Approval (Initial Target – 6-8 months)
- *STATUS – IRB approval at all sites with the primary site being approved on 26 February 2015 and the last sub-site approval on 25 February 2016*

Milestone 2: Target recruitment met (Initial Target – 24 months)
- *STATUS- The actual data collection sites did not receive IRB approval until 2016. Currently enrolled as of 30 September 2016: 173 subjects (113 at WBAMC and 60 at WAMC).*

Milestone 3: 1-year injury surveillance complete (Initial Target – 36 months)
- *STATUS - - Currently, no subject has been enrolled for the one year mark. The first subject was enrolled on 2 FEB 2016. Therefore, this analysis has not started*

Milestone 4: Analysis for Primary Aims complete (42 months)
- *STATUS - (not started)*

What was accomplished under these goals?
1) Major activities
    a. We were granted IRB approval from the main site on 26 February 2015, however, our sub-sites were not given IRB approval until early 2016. We were told that this delay was caused by the delays from the Defense Health Agency's termination of the contract with IRBNet. The main site is not where we opted to put our primary support, so they are actually not collecting any data there (support for research changed from the time support letters were signed to 18+ months later with different leadership, when the study was ready to begin).
    b. The following is our timeline and processes leading up to this point related to regulatory approval:
    a. We submitted the core protocol to the IRB at Madigan Army Medical Center in November 2014.
    b. We received approval by the Madigan IRB for the project on 26 February, 2015.
    c. The Site Specific Addendums (SSA) for the other 3 sites (WBAMC, Womack, and BAMC) were submitted in March, 2015.
    d. The final Site Specific Addendum was approved 25 February 2016.
    e. We executed training trips and sessions for all research staff by the end of the 2015 year.
    f. The study has been registered on clinicaltrials.gov : https://clinicaltrials.gov/ct2/show/NCT02776930

2) Specific objectives:
    a. Continue recruitment of subjects at WBAMC and WAMC and begin enrollment at BAMC

3) Significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or
N/A at this time

4) Other achievements. N/A at this time

What opportunities for training and professional development has the project provided?

Training was provided to all the physical therapy staff at 2 of the large hospitals (William Beaumont Army Medical Center and Womack Army Medical Center). The consultants (Dr. Plisky, Dr. Kiesel, and Dr. Butler) traveled to these sites to provide training for research staff, but also allowed other hospital staff to attend the training.

Due to the delay in being granted IRB approval, several of the Active Duty Military personnel that we originally trained have left their respective sites due to retiring, deployment, or having a permanent change of station. We have updated the protocol to reflect this and will conduct additional training sessions for the new research staff by the end of the 2016 year.

The key investigators of this team presented a 2-hour educational breakout session on injury prediction/prevention titled "Prediction, Prevention, and Preemption: Screening for sports and training injuries. What are the possibilities?" The talk was presented to a national audience at the American Physical Therapy Association annual Combined Sections Meeting, February, 2015.

How were the results disseminated to communities of interest?
Nothing to report

What do you plan to do during the next reporting period to accomplish the goals?
We are working diligently on improving our recruitment numbers by focusing on issues and barriers that may be limiting enrollment. We are educating the local site staff on the recruitment needs and improving the screening process. In addition, BAMC will begin to recruit subjects as outlined in the protocol in order to increase our recruitment numbers.

In addition to improving enrollment, the subjects who were enrolled early in this process will have completed their one year follow period. We will begin to pull and analyze the data for those subjects.

IMPACT:

What was the impact on the development of the principal discipline(s) of the project?
There is no increased burden on the Physical Therapy department other than identifying potential candidates as the enrollment process begins as the potential subject is being discharged from Physical Therapy. It turns out that many patients are not formally discharged from rehabilitation. Many of them "self-discharge" and just stop coming back, either due to training or other conflicts. This potentially illuminates another issue and problem with rehabilitation efforts after an injury in this population.

What was the impact on other disciplines?
Nothing to Report

What was the impact on technology transfer?
Nothing to Report

What was the impact on society beyond science and technology?
Nothing to Report

CHANGES/PROBLEMS:

Changes in approach and reasons for change We are in the process of assessing entrance to the study upon return to duty from any location, as that is really the fundamental question. Whether they are cleared to return to duty after formal rehabilitation or directly from their primary care provider, the fact is that they have been cleared to return to full duty, and that is the actual construct we are attempting to capture: performance when cleared to return to duty after injury.

Actual or anticipated problems or delays and actions or plans to resolve them
We were granted IRB approval from the main site on 26 February 2015, however, our final Site Specific Addendum was approved 25 February 2016. We were told that this delay was caused by the delays from the

Defense Health Agency's termination of the contract with IRBNet. Due to this delay, our current recruitment/enrolled numbers are lower than we had originally planned for. Since low enrollment is our main issue, we are to begin enrolling subjects at BAMC by the end of the 2016 year.

It turns out that many patients are not formally discharged from rehabilitation. Many of them "self-discharge" and just stop coming back, either due to training or other conflicts. This potentially illuminates another issue and problem with rehabilitation efforts after an injury in this population.

Changes that had a significant impact on expenditures
The delay in starting the project related to IRB approval means that we have had 2 FTE research physical therapists working and on payroll for approximately 8 months prior to enrolling the first subject. This may have a significant impact on the tail end of our project depending on how our enrollment numbers pan out.

In addition, there have been several issues with the MP3 software and this has required multiple revisions. With each revision being an additional cost, this again may have a significant impact on our tail end of the project.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
None

Significant changes in use or care of human subjects None

Significant changes in use or care of vertebrate animals. N/A

Significant changes in use of biohazards and/or select agents N/A

PRODUCTS: Nothing to Report

Publications, conference papers, and presentations
None

Journal publications. None

Books or other non-periodical, one-time publications. None

Other publications, conference papers, and presentations. None

Website(s) or other Internet site(s)
None

Technologies or techniques
None

Inventions, patent applications, and/or licenses
None

Other Products
None

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS
What individuals have worked on the project?

Name:	*MAJ Dan Rhon*
Project Role:	*Primary Investigator*

Researcher Identifier (e.g. ORCID ID):	*0000-0002-4320-990X*
Nearest person month worked:	*9*
Contribution to Project:	*Writing IRB protocols for all 4 sites; Coordinating training at 2 main sites. Traveled to all 4 sites for site visits, coordinate with local IRBs, and help deliver training to research team. Continued oversight of all sites.*
Funding Support:	*N/A*

Name:	*Dr. Matt Hartshorne*
Project Role:	*Research Physical Therapist*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*9*
Contribution to Project:	*Local assistance with IRB at Womack site. Assistance with setting up and planning local training meeting. Putting together study material for local site. In charge of enrollment/recruitment at local site. Updating protocols and other IRB documents as necessary.*
Funding Support:	*N/A*

Name:	*Dr. Danielle Langness*
Project Role:	*Research Physical Therapist*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*9*
Contribution to Project:	*Local assistance with IRB at WBAMC site. Assistance with setting up and planning local training meeting. Putting together study material for local site. In charge of enrollment/recruitment at local site. Updating protocols and other IRB documents as necessary.*
Funding Support:	*N/A*

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
Due to the delay in being granted IRB approval, several of the Active Duty Military personnel that we originally trained have left their respective sites due to retiring, deployment, or having a permanent change of station (site PIs). We have updated the protocol to reflect this and will conduct additional training sessions for the new research staff by the end of the 2016 year. Dr. Robert Butler has taken a new job and unable to continue being engaged with the project.

What other organizations were involved as partners?
Nothing to report

SPECIAL REPORTING REQUIREMENTS
COLLABORATIVE AWARDS: N/A

QUAD CHARTS: *Attached*

1. **APPENDICES:** None

Development of Predictive Models of Injury for the Lower Extremity, Lumbar, and Thoracic Spine after Discharge from Physical Rehabilitation

ERMS# 13063063.
Award # W81XWH-14-2-0141

**PI:** MAJ Daniel Rhon   **Org:** The Geneva Foundation   **Award $**1,084,186

Study/Product Aim(s)

•**Aim 1:** To improve prediction of injury-free, we will compare and contrast select performance test results in service members that sustain an injury versus those that do not during the 12-month follow-up period.

•**Aim 2:** Develop predictive models from collected variables in order to derive a multi-factorial injury risk prediction algorithm.

•**Aim 3**: Develop an optimal physical performance standard that should be met prior to discharge from medical care with the aim of decreasing future injury risk and facilitating successful injury-free return to duty.

Approach

- Screen 480 Soldiers being discharged after injury to return to full duty
- Prospectively follow them for one year to identify injuries.
- Screening process includes movement and balance screens, measures of power, demographic data and biopsychosocial measures.
- Injury data will be collected through self-report, profile data, and healthcare utilization data. Clinical prediction rules will be used for algorithm development.

Accomplishment: Project has begun, and we are about 1/3 of our way through recruitment.
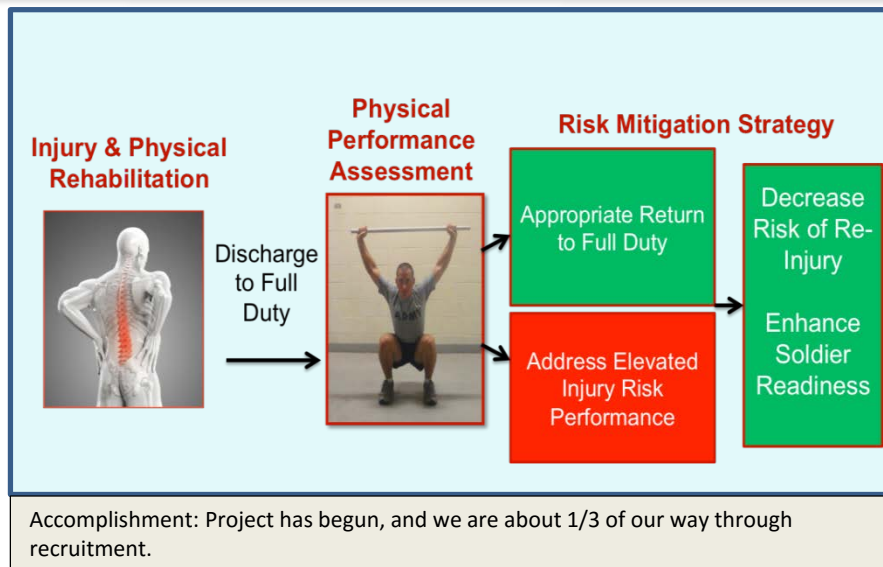
Activities	FY	14	15	16	17
IRB Approval, hiring and training of support personnel			▅▅▅		
Subject enrollment and data collection and 1-year follow-up.			▅▅▅▅	▅▅▅	
Healthcare utilization pull from DoD database & medical records					▅▅
Data analysis, interpretation, prediction model derivation, and reporting of results					▅▅
Estimated Budget ($1084K)		$407K	$380K	$237K	$60K

Updated: 21 October 2016

Goals/Milestones

CY14 Goal – System Development/Demonstration
☑ Optimal testing pathways established & tested

CY15 Goals – Data Collection
☑ IRB protocol submission/approval (final approval in Feb 2016)
☑ HRPO Approval
☑ Subject recruitment began in March 2016)
☑ Collect follow up data regarding Injuries incurred (began 2016)

CY16 Goal – Data Collection (and final IRB approval)

CY17 Goal – Data Collection/Analysis
❑ Analyze data to determine greatest predictors of injury risk
❑ Develop prediction algorithms based on findings
❑ TMA approval for healthcare utilization data pull from PASBA

CY18 Goal
❑ Risk mitigation strategies developed and linked to predictor variables

Comments/Challenges/Issues/Concerns
We were behind schedule due to delays in receiving IRB approval for all sites (over 1 year to gain) Everything is flowing smoothly, but just a little behind still.

Budget Expenditure to date
Projected Expenditure: $1.0M   Actual Expenditure: $415K